July 2, 2024

Balt USA, LLC
Alicia Smith
Senior Regulatory Affairs Specialist
29 Parker
Irvine, California 92618

Re: K234083
Trade/Device Name: Next Generation Aspiration Catheter; Balt Aspiration Tubing Set
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NRY
Dated: May 31, 2024
Received: June 3, 2024

Dear Alicia Smith:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801; medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Naira Muradyan -S

Naira Muradyan, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K234083

Device Name
Next Generation Aspiration Catheter; Balt Aspiration Tubing Set

Indications for Use *(Describe)*

Next Generation Aspiration Catheter:
The Next Generation Aspiration Catheter with a compatible aspiration pump and Balt Aspiration Tubing Set is indicated for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral - M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset.

Patients who are ineligible for intravenous tissue plasminogen activator (IV-tPA) or who fail IV-tPA therapy are candidates for treatment.

Balt Aspiration Tubing Set:
The Balt Aspiration Tubing Set is intended to connect the Next Generation Aspiration Catheter to the canister of a compatible aspiration pump and to allow the user to control the fluid flow.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary: K234083

Applicant:	Balt USA, LLC 29 Parker Irvine, CA 92618 Registration No.: 3014162263
Contact Person:	Alicia Smith Senior Specialist, Regulatory Affairs Email: alicia.smith@baltgroup.com

Date Summary Prepared:	June 28, 2024
Trade Name:	Next Generation Aspiration Catheter; Balt Aspiration Tubing Set
Common Name:	Catheter, Thrombus Retriever
Review Panel:	Neurology
Product Code:	NRY
Regulation Number:	21 CFR 870.1250
Regulation Name:	Percutaneous Catheter
Device Classification:	Class II
Predicate Device:	ZOOM 71 Reperfusion Catheter; ZOOM Aspiration Tubing 510(k)#: K211476

Device Description:
The Next Generation Aspiration Catheter is a single-lumen, coil reinforced, variable stiffness composite catheter that facilitates removal of thrombus from the neurovasculature when connected to a compatible aspiration pump and the Balt Aspiration Tubing Set. The Next Generation Aspiration Catheter is comprised of a hollow cylindrical tube which incorporates a standard luer fitting to allow attachment of ancillary devices for navigation, infusion of fluids, and aspiration through the catheter. The wall of the tube is constructed using a combination of metal coils and medical grade polymers. The distal portion of the Next Generation Aspiration Catheter has a hydrophilic coating which provides a lubricious surface during use to aid in tracking through the vasculature. The distal tip of the catheter includes a radiopaque marker providing the user with visual confirmation of the distal tip location under fluoroscopy. The Next Generation Aspiration Catheter is offered in various working lengths and nominal inner diameters and outer diameters.

An introducer sheath is provided in the package to support and facilitate the insertion of the Next Generation Aspiration Catheter's distal tip into an appropriate vascular sheath.

The catheter and introducer sheath are provided sterile, non-pyrogenic, and are intended for single use only.

The Balt Aspiration Tubing Set is comprised of a hollow cylindrical tube which is bonded to a standard luer fitting that connects to the Next Generation Aspiration Catheter and a slip fit connector that connects to the canister on the aspiration pump. The Balt Aspiration Tubing Set is made of common medical grade polymers, is provided sterile, and is intended for single use only.

The Next Generation Aspiration Catheter and Balt Aspiration Tubing Set are intended to be used with:

- Guidewires

- Guide Sheaths
- Aspiration Pump

Indications for Use:

Next Generation Aspiration Catheter:
The Next Generation Aspiration Catheter with a compatible aspiration pump and Balt Aspiration Tubing Set is indicated for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral - M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset.

Patients who are ineligible for intravenous tissue plasminogen activator (IV-tPA) or who fail IV-tPA therapy are candidates for treatment.

Balt Aspiration Tubing Set:
The Balt Aspiration Tubing Set is intended to connect the Next Generation Aspiration Catheter to the canister of a compatible aspiration pump and to allow the user to control the fluid flow.

Comparison of Technological Characteristics:

	Predicate Device	**Subject Device**
	ZOOM 71 Reperfusion Catheter; ZOOM Aspiration Tubing (K211476)	**Next Generation Aspiration Catheter; Balt Aspiration Tubing Set (K234083)**
Indications for Use	The ZOOM Reperfusion Catheters, with the ZOOM Aspiration Tubing and ZOOM Aspiration Pump (or equivalent vacuum pump), are indicated for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral – M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment. The ZOOM Aspiration Tubing is intended to connect the ZOOM Reperfusion Catheter to the ZOOM Canister of the ZOOM Aspiration Pump and to allow the user to control the fluid flow.	Next Generation Aspiration Catheter: The Next Generation Aspiration Catheter with a compatible aspiration pump and Balt Aspiration Tubing Set is indicated for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral - M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV-tPA) or who fail IV-tPA therapy are candidates for treatment. Balt Aspiration Tubing Set: The Balt Aspiration Tubing Set is intended to connect the Next Generation Aspiration Catheter to the canister of a compatible aspiration pump and to allow the user to control the fluid flow.

	Predicate Device	Subject Device	
	ZOOM 71 Reperfusion Catheter; ZOOM Aspiration Tubing (K211476)	**Next Generation Aspiration Catheter; Balt Aspiration Tubing Set (K234083)**	
Device Classification/ Product Code	Class II / NRY (Percutaneous Catheter)	Same as K211476	
Intended Use	Revascularization of patients with acute ischemic stroke.	Same as K211476	
Dimensional Specifications	ZOOM 71 Reperfusion Catheter	NG 071 ASP	NG 074 ASP
Inner Diameter	0.071”	Same as K211476	0.074”
Outer Diameter	Proximal: 0.086” Distal: 0.085”	Proximal: 0.083” Distal: 0.082”	Proximal: 0.086” Distal: 0.085”
Effective Length	137 cm	128 cm, 132 cm	120 cm, 132 cm
Device Attributes			
Materials	Commonly used medical grade plastics & metals with hydrophilic coating.	Same as K211476	
Coating	Hydrophilic	Same as K211476	
Packaging Configuration	The catheter is placed in a protective polyethylene tube and then mounted, along with the accessories, onto a polyethylene packaging card. The packaging card is inserted into a Tyvek® pouch which is then sealed. The sealed pouch and IFU are placed in a carton box.	Same as K211476	
Shelf Life	12 months	12 months (Next Generation Aspiration Catheter) 6 months (Balt Aspiration Tubing Set)	
Sterilization			
Condition Supplied	Sterile and Single Use	Same as K211476	
Method	Ethylene Oxide (EO), SAL 10^{-6}	Same as K211476	
Accessories			
Accessories	None	Introducer Sheath	
Aspiration Tubing	ZOOM Aspiration Tubing	Balt Aspiration Tubing Set	
Dimensional Specifications	Length: 104” Inner Diameter: 0.110” Minimum	Length: 114” Inner Diameter: 0.110” ± 0.003”	
Condition Supplied	Sterile and Single Use	Same as K211476	
Sterilization Method	Ethylene Oxide (EO), SAL 10^{-6}	Same as K211476	
Flow Control Mechanism	Flow Control Clamp	Flow Control Valve	
Aspiration Pump	• Capable of achieving pressure between -20 inHg to -29.9 inHg • Airflow rating of 0 – 23 LPM • IEC 60601-1 Compliant	• Capable of achieving pressure between -20 inHg and -25.6 inHg • Airflow rating ≥ 16 LPM	

Performance Testing Summary:

Biocompatibility:

The following biocompatibility testing was conducted for the Next Generation Aspiration Catheter:

Test	Test Method Summary	Conclusion
Cytotoxicity – MEM Elution	Tested in accordance with ISO 10993-5	Pass The test article is considered non-cytotoxic.
Hemocompatibility – Hemolysis (Direct Contact & Extract Method)	Tested in accordance with ISO 10993-4	Pass The test article is considered non-hemolytic.
Hemocompatibility – Complement Activation SC5b-9 Assay	Tested in accordance with ISO 10993-4	Pass Requirements have been met by the test article.
Hemocompatibility – Partial Thromboplastin Time (PTT)	Tested in accordance with ASTM F2382-18	Pass Requirements have been met by the test article.
Hemocompatibility – Blood Platelet and Leukocyte Count (PLC)	Tested in accordance with ASTM F2888-19	Pass Requirements have been met by the test article.
Hemocompatibility – Comparative Surface Assessment	The test article was visually inspected at more than 40x magnification.	Pass Requirements have been met by the test article.
Hemocompatibility – Thrombogenicity in a Canine Model	Tested in accordance with ISO 10993-4	Pass The test article performed similarly to the comparator.
Pyrogenicity – Material-Mediated Rabbit Pyrogen	Tested in accordance with USP <151>	Pass Requirements have been met by the test article.
Sensitization – Guinea Pig Maximization Sensitization	Tested in accordance with ISO 10993-10	Pass The test article did not elicit a sensitization response.
Systemic Toxicity – Acute Systemic Injection	Tested in accordance with ISO 10993-11	Pass Requirements have been met by the test article.
Irritation – Intracutaneous Reactivity	Tested in accordance with ISO 10993-23	Pass Requirements have been met by the test article.

The following biocompatibility testing was conducted for the Balt Aspiration Tubing Set:

Test	Test Method Summary	Conclusion
Cytotoxicity	Tested in accordance with ISO 10993-5	Pass The test article is considered non-cytotoxic.

Test	Test Method Summary	Conclusion
Sensitization	Tested in accordance with ISO 10993-10	Pass The test article did not elicit a sensitization response.
Irritation	Tested in accordance with ISO 10993-23	Pass Requirements have been met by the test article.

Performance Data – Bench:

The following performance bench testing was conducted for the Next Generation Aspiration Catheter:

Test	Test Method Summary	Results
Dimensional Verification	The catheter outer diameter, inner diameter, usable length, tip length, and coating length were measured.	Pass
Surface Contamination	Visual inspection completed for surface defects.	Pass
Tensile Strength	The peak tensile force was evaluated per ISO 10555-1 after preconditioning in a simulated use model.	Pass
Kink Resistance	Kink resistance was evaluated after preconditioning in a simulated use model.	Pass
Liquid Leakage	The device was exposed to a liquid pressure for 30 seconds. The device was inspected for leakage per ISO 10555-1.	Pass
Air Leakage	The device was tested for air leakage into the hub per ISO 10555-1.	Pass
Dynamic Burst	Tests to verify the device can withstand internal liquid pressure under dynamic flow conditions with the distal end open.	Pass
Torque Strength	The device was evaluated for torque strength by measuring the number of catheter rotations until failure after preconditioning in a simulated use model and compared to the predicate.	Pass
Hub Validation Testing	The device shall meet the established acceptance criteria per ISO 80369-7.	Pass
Particulate Matter	The catheter underwent simulated use testing and particulate testing was conducted including a reference device for comparison.	Pass
Tip Buckling	The maximum force to cause catheter tip buckling while constrained at varying distances was measured.	The tip stiffness was comparable to the predicate and other cleared aspiration catheters.
Corrosion	Corrosion tested per ISO 10555-1.	No evidence of corrosion and met requirements per ISO 10555-1.
Static Burst	The distal tip of the catheter was blocked, and fluid was injected into the lumen at increasing pressure until the catheter burst per ISO 10555-1 and the static burst pressure was compared with the maximum pressure generated with manual syringe injection.	Pass

Test	Test Method Summary	Results
Coating Integrity	The coating integrity was inspected before and after preconditioning through a simulated use model.	No evidence of surface damage or coating defects.
Saline and Contrast Exposure	After the device was used to deliver saline and contrast media, the device was inspected for damage, and dimensional attributes were measured.	No visual evidence of damage or dimensional changes.
Radiopacity (Visibility)	The device was tested to demonstrate acceptable radiopacity.	Marker radiopacity is comparable to the predicate.
Design Validation /Usability	The subject and predicate devices were prepared in accordance with their respective instructions for use and tested for device usability in a clinically relevant anatomical model.	Device preparation, introduction, trackability, and retrieval were comparable to the predicate.
Lumen Collapse	Tested to verify that the catheter lumen does not collapse at maximum vacuum pressure for a duration of 6 minutes.	Pass
Vacuum Pressure	Tested to verify the vacuum pressure at the aspiration pump and distal tip of the catheter.	Pass

The following performance bench testing was conducted for the Balt Aspiration Tubing Set:

Test	Test Method Summary	Results
Dimensional Verification	The total length, inner diameter, and outer diameter were measured.	Pass
Surface Contamination	Surface contamination testing was performed in alignment with ISO 10555-1.	Pass
Lumen Collapse	Tested to verify that the aspiration tubing lumen does not collapse at maximum vacuum pressure for a duration of 6 minutes.	Pass
Tensile Strength	Testing was adopted from EN ISO 10555-1.	Pass
Tubing to Pump	The tubing to pump pressure was measured.	Pass
On/Off Functionality	The On/Off functionality of the tubing set was measured.	Pass
Tubing Hub Compatibility	The tubing hub compatibility was evaluated.	Pass

Sterilization and Shelf Life:
The Next Generation Aspiration Catheter and Balt Aspiration Tubing Set are sterilized using an ethylene oxide sterilization cycle that was verified to a sterility assurance level of 1×10^{-6} in accordance with ISO 11135. Accelerated aging testing for the Next Generation Aspiration Catheter and Balt Aspiration Tubing

Set based on ASTM F1980 have established that the subject device and packaging remain functional for the labeled expiration date. Aging studies for packaging integrity, seal strength, and device functionality were performed and met the acceptance criteria.

Performance Data – Animal:
The safety and performance of the Next Generation Aspiration Catheter and Balt Aspiration Tubing Set were evaluated in a comparative animal study conducted under Good Laboratory Practices in a porcine model in the internal maxillary artery (IMAX), superficial cervical artery (SCA), renal artery, femoral artery, and lingual vessels against the control (ZOOM 71 Reperfusion Catheter and Tubing Set). Assessments included performance and handling, aspiration of experimental soft and firm clots, and application of maximum vacuum with the device in a wedged position against the vessel wall. Both the subject and the control devices were evaluated at subacute (3 days) and chronic (30 days) time points. Performance and handling, soft and firm clot aspiration, and wedge assessment results were comparable between the test and control devices. Angiographic and histological evaluations concluded the devices were comparable at all time points.

Performance Data – Clinical:
A determination of substantial equivalence is based upon successful completion of nonclinical bench and animal testing.

Conclusion:
The Next Generation Aspiration Catheter and Balt Aspiration Tubing Set have the same intended use as the predicate device. The differences in technological characteristics in comparison to the predicate device do not raise different or new questions of safety and effectiveness. The successful completion of nonclinical bench, biocompatibility, sterilization, shelf life, and animal testing supports that the subject device is substantially equivalent to the predicate device.